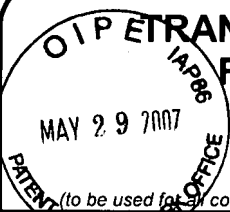


5-30-07


PTO/SB/21 (09-04)

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

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 (to be used for correspondence after initial filing)	Application Number	10/561, 603
	Filing Date	March 29, 2007
	First Named Inventor	Jong Joseph Kim
	Art Unit	1615
	Examiner Name	To Be Determined
Total Number of Pages in This Submission	Attorney Docket Number	VGX0001-100

ENCLOSURES (check all that apply)		
<input type="checkbox"/> Fee Transmittal Form <input type="checkbox"/> Fee Attached <input type="checkbox"/> Amendment / Reply <input type="checkbox"/> After Final <input type="checkbox"/> Affidavits/declaration(s) <input type="checkbox"/> Extension of Time Request <input type="checkbox"/> Express Abandonment Request <input checked="" type="checkbox"/> Information Disclosure Statement <input type="checkbox"/> Certified Copy of Priority Document(s) <input type="checkbox"/> Reply to Missing Parts/ Incomplete Application <input type="checkbox"/> Reply to Missing Parts under 37 CFR1.52 or 1.53	<input type="checkbox"/> Drawing(s) <input type="checkbox"/> Licensing-related Papers <input type="checkbox"/> Petition <input type="checkbox"/> Petition to Convert to a Provisional Application <input type="checkbox"/> Power of Attorney, Revocation Change of Correspondence Address <input type="checkbox"/> Terminal Disclaimer <input type="checkbox"/> Request for Refund <input type="checkbox"/> CD, Number of CD(s) _____ <input type="checkbox"/> Landscape Table on CD	<input type="checkbox"/> After Allowance Communication to TC <input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences <input type="checkbox"/> Appeal Communication to TC (Appeal Notice, Brief, Reply Brief) <input type="checkbox"/> Proprietary Information <input type="checkbox"/> Status Letter <input checked="" type="checkbox"/> Other Enclosure(s) (please identify below): Forms SB/08a and SB/08b (4 pp.); (83) References Cited, (40) References Enclosed. 4
Remarks EXPRESS MAIL LABEL NO: ED366576330US DATE OF DEPOSIT: 5/29/2007		

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT			
Firm	Pepper Hamilton LLP		
Signature			
Printed Name	Mark DeLuca		
Date	5/29/07	Reg. No.	33,229

CERTIFICATE OF TRANSMISSION/MAILING			
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DOCKET NO.: VGX0001-100

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of: **Jong Joseph Kim**

Serial No.: **10/561,603**

Group Art Unit: **1615**

Filing Date: **March 29, 2007**

Examiner: **To Be Determined**

For: **Compositions For And Methods For Treating HIV**

EXPRESS MAIL LABEL NO.: ED366576330US

DATE OF DEPOSIT: 5/29/2007

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

INFORMATION DISCLOSURE STATEMENT

Pursuant to 37 C.F.R. §§ 1.56 and in accordance with 37 C.F.R. §§ 1.97 and 1.98, information relating to the above-identified application is hereby disclosed, the Examiner in charge of the above-identified application is requested to consider and make of record the references listed on the PTO Form SB08A and PTO Form SB/08B, formerly known as PTO Form 1449 submitted herewith.

Inclusion of the information submitted herewith is not to be construed as an admission that the information is material as that term is defined in 37 C.F.R. § 1.56(b).

In accordance with 37 C.F.R. § 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made.

This Information Disclosure Statement is being filed:

- ☐ within three months of the filing date of the patent application.
- ☐ within three months of the date of entry into the national stage as set forth in 37 C.F.R. § 1.491 of the international application.
- ☒ **before** the mailing date of a first Office Action on the merits.
- ☐ **after** the mailing date of a first Office Action on the merits, but before the mailing date of a Final Office Action under 37 C.F.R. § 1.116 or a Notice of Allowance under 37 C.F.R. § 1.311, and accordingly is accompanied by:
 - ☐ the Statement under 37 C.F.R. § 1.97(e) (see “Statement” below);
 - or**
 - ☐ the Fee of \$180.00 set forth in 37 C.F.R. § 1.17(p); or
 - ☐ No fee is owed by the applicant(s).
- ☐ In accordance with 37 C.F.R. § 1.129(a), this Information Disclosure Statement is being filed in connection with ☐ the first or ☐ second After Final Submission, and accordingly is accompanied by the Statement under 37 C.F.R. § 1.97(e) (see “Statement” below) and the fee of \$180.00 as set forth in 37 C.F.R. § 1.17(p), is attached.
- ☐ **after** the mailing date of a Final Office Action under 37 C.F.R. § 1.116 or a Notice of Allowance under 37 C.F.R. § 1.311, but before the payment of the Issue Fee, and accordingly is accompanied by the Statement under 37 C.F.R. § 1.97(e), (see “Statement,” and “Fees” below).
- ☒ Copies of the references listed on the attached PTO Forms SB/08a and SB/08b, formerly known as PTO Form 1449 are enclosed.

EXCEPT THAT:

- ☐ In view of the voluminous nature of reference @@, and the likelihood that this reference is available to the Examiner, copies are not enclosed herewith.
- ☐ In accordance with 37 C.F.R. § 1.98(d), copies of the following references listed on the attached PTO Form SB/08A and PTO Form SB/08B, formerly known as PTO Form 1449 are not enclosed herewith because they were previously cited by or submitted to the U.S. Patent and Trademark Office in patent application(s) for which a claim for priority under 35 U.S.C. § 120 have been made in the instant application.
- ☐ If any of the foregoing publications are not available to the Examiner, Applicant will endeavor to supply copies at the Examiner's request.

Statement under 37 C.F.R. § 1.97(e)

- ☐ The undersigned attorney hereby states that each item information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign patent application not more than three months prior to the filing of the Information Disclosure Statement.

Fees

- ☒ No Fee is owed by the applicant(s).
- ☐ The Information Disclosure Statement Fee of \$180.00 under 37 C.F.R. § 1.17(p) is enclosed herewith.

Method of Payment of Fees

- ☐ Attached is a check in the amount of \$ _____. This form is submitted in duplicate.
- ☐ Charge Deposit Account No. 50-1275 in the amount of \$180.00. This form is submitted in duplicate.
- ☒ Please charge any deficiency or credit any overpayment to Deposit Account 50-0436.
- ☐ No fee or Statement is required under 37 C.F.R. § 1.97(b).

Respectfully submitted,



Mark DeLuca
Registration No. 33,229

Dated:

5/29/07

PEPPER HAMILTON LLP
500 Grant Street, 50th Floor
Pittsburgh, PA 15219
Tel: 610.640.7855
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Sheet	1	of	6
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U.S. PATENT DOCUMENTS

Examiner Initials *	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number - Kind Code ² (if known)			
	1	US- 2,142,170	01-03-1939	Bockmuhl et al.	
	2	US- 3,133,132	05-12-1964	S. Loeb et al.	
	3	US- 3,143,288	08-04-1964	Biegel	
	4	US- 3,173,876	03-16-1965	John C. Zobrist	
	5	US- 3,214,431	10-26-1965	Rao et al.	
	6	US- 3,276,586	10-04-1966	N.O. Rosaen	
	7	US- 3,541,005	11-17-1970	Strathmann et al	
	8	US- 3,541,006	11-17-1970	Bixler et al.	
	9	US- 3,546,876	12-15-1970	Fokker et al.	
	10	US- 3,651,049	03-21-1972	Boissier et al.	
	11	US- 3,832,252	08-27-1974	Higuchi et al.	
	12	US- 3,845,770	11-05-1974	Theeuwes et al.	
	13	US- 3,854,480	12-17-1974	Zaffaroni	
	14	US- 3,916,899	11-04-1975	Theeuwes et al.	
	15	US- 3,954,970	05-04-1976	Weinstein et al.	
	16	US- 4,008,719	02-22-1977	Theeuwes et al.	
	17	US- 4,014,334	03-29-1977	Theeuwes et al.	
	18	US- 4,058,122	11-15-1977	Theeuwes et al.	
	19	US- 4,116,241	09-26-1978	Theeuwes et al.	
	20	US- 4,160,020	07-03-1979	Ayers	

FOREIGN PATENT DOCUMENTS

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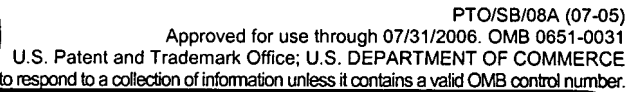
Examiner
Signature

Date
Considered

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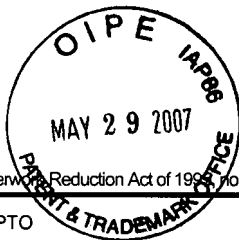
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Sheet	2	of	6
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Application Number	10/561,603
Filing Date	March 29, 2007
First Named Inventor	DOUG ROSEPIA KIM
Art Unit	1615
Examiner Name	To Be Determined
Attorney Docket Number	VEX 0001-100

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STATEMENT BY APPLICANT**

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Sheet 3 of 6

Complete if Known

Application Number	10/561,603
Filing Date	March 29, 2007
First Named Inventor	Jong Joseph Kim
Art Unit	1615
Examiner Name	To Be Determined
Attorney Docket Number	VGX0001-100

NON PATENT LITERATURE DOCUMENTS

Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	41	Chantal Petit, A.J. et al. "Human immunodeficiency virus infection down-regulates HLA class II expression and induces differentiation in promonocytic U937 cells," (1987) <i>J. Clin. Invest.</i> 79:1883	
	42	Cohen, B.A., et al, "Human immunodeficiency virus vpr product is a virion-associated regulatory protein," <i>J. Virol.</i> (1999) 64:3097-3099.	
	43	Croxtall et al., "Lipocortin 1 mediates dexamethasone-induced growth arrest of the A549 lung adenocarcinoma cell line," <i>Proc. Natl. Acad. Sci. USA</i> (1992), 89:3571-5.	
	44	Dedera, D., et al. "Viral protein R of human immunodeficiency virus types 1 and 2 is dispensable for replication and cytopathogenicity in lymphoid cells," <i>J. Virol.</i> (1989) 63:3205-3208.	
	45	Foldesi et al., "Determination of RU486 (mifepristone) in blood by radioreceptorassay; A pharmacokinetic study," <i>Contraception</i> 56 (1996), pp. 27-32	
	46	Fryer C. et al., "Selective Activation of the Glucocorticoid Receptor by Steroid Antagonists in Human Breast Cancer and Osteosarcoma Cells," <i>J. Biol. Chem</i> (2000), 275: 17771-17777	
	47	Gallo, R.C. et al." Frequent detection and isolation of cytopathic retroviruses (HTLV-III) from patients with AIDS and at risk for AIDS," <i>Science</i> (1984) 224:500-503.	
	48	Griffin, G.E. et al., "Activation of HIV gene expression during monocyte differentiation by induction of NF-kB," <i>Nature</i> (1989), 339:70-73.	
	49	Gross, Neil D. et al., "Spironolactone Blocks Glucocorticoid-Mediated Hearing Preservation in Autoimmune Mice," <i>Laryngoscope</i> (2002), 112: 298-303.	
	50	Kekkonen et al., "Pharmacokinetics of mifepristone after low oral doses," <i>Contraception</i> 54 (1996), pp. 229-234.	
	51	Hattori, N., et al., "The human immunodeficiency virus type 2 vpr gene is essential for productive infection of human macrophages," <i>Proc. Natl. Acad. Sci. USA</i> (1990) 87:8080-8084.	

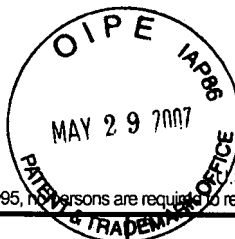
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Sheet 4 of 6

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Application Number	10/561,603
Filing Date	March 29, 2007
First Named Inventor	Jong Joseph Kim
Art Unit	1615
Examiner Name	To Be Determined
Attorney Docket Number	VGX0001-100

NON PATENT LITERATURE DOCUMENTS

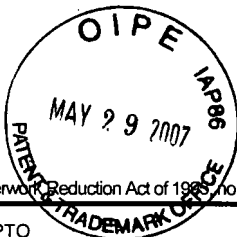
Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	52	Heikenheimo et al., "Dose-response relationships of RU 486," <i>Ann. Med.</i> 1993 Feb; 25(1):71-6.	
	53	Heikenheimo O. "Pharmacokinetics of the antiprogestosterone RU 486 in women during multiple dose administration," <i>J. Steroid Biochem</i> (1989), 32(1A) pp. 21-25.	
	54	Honer C. et al., "Glucocorticoid Receptor Antagonism by Cyproterone Acetate and RU486," <i>Mol Pharm</i> (2003), 63:1012-1020.	
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	56	Jang et al., "Identification of CYP3A4 as the principal enzyme catalyzing mifepristone (RU 486) oxidation in human liver microsomes," <i>Biochem. Pharmacol.</i> (1996) 52:753-761.	
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	59	Levy, J.A. et al., "Isolation of lymphocytopathic retroviruses from San Francisco patients with AIDS," (1984) <i>Science</i> 225:840-842.	
	60	Li, G. et al., "Human immunodeficiency virus type 1 DNA synthesis, integration, and efficient viral replication in growth-arrested T cells," <i>J. Virol.</i> (1993) 67:3969-77.	
	61	Myers, G. et al., "The emergence of simian/human immunodeficiency viruses," <i>AIDS Res. Hum. Retrovir.</i> (1992) 8:373-86.	
	62	Naylor et al., "Antiglucocorticoids: in vivo assay and evaluation of cortexolone, progesterone, and 6-beta-bromoprogesterone," <i>Endocrinology</i> 1980, 107: 117-121	

Examiner Signature		Date Considered	
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Sheet 5 of 6

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Application Number	10/561,603
Filing Date	March 29, 2007
First Named Inventor	Jong Joseph Kim
Art Unit	1615
Examiner Name	To Be Determined
Attorney Docket Number	VGX0001-100

NON PATENT LITERATURE DOCUMENTS

Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	63	Ogawa, K., et al., "Mutational analysis of the human immunodeficiency virus vpr open reading frame," <i>J. Virol.</i> (1989) 63:4110-4114.	
	64	Pariante C.M. et al., "The steroid receptor antagonists RU40555 and RU486 activate glucocorticoid receptor translocation and are not excreted by the steroid hormones transporter in L929 cells," <i>J Endocrinol.</i> 2001, 169:309-320.	
	65	Reilly et al., "Mechanism-based inhibition of rat liver microsomal diazepam C3-hydroxylase by mifepristone associated with loss of spectrally detectable cytochrome P450," <i>Chem Biol. Interact.</i> (1999), 118(1):39-49.	
	66	Rich, E.A. et al., "Increased susceptibility of differentiated mononuclear phagocytes to productive infection with human immunodeficiency virus-1 (HIV-1).," <i>J. Clin. Invest.</i> (1992) 89:176-83.	
	67	Rose, R.M. et al., "Frequent identification of HIV-1 DNA in bronchoalveolar lavage cells obtained from individuals with the acquired immunodeficiency syndrome," <i>Am. Rev. Respir. Dis.</i> (1986) 143:850-854.	
	68	Roulston, A. et al., "Induction of monocytic differentiation and NF-kappa B-like activities by human immunodeficiency virus 1 infection of myelomonoblastic cells," (1992) <i>J. Exp. Med.</i> 175:751-63.	
	69	Salahuddin, S.Z. et al., "Human T lymphotropic virus type III infection of human alveolar macrophages," <i>Blood</i> (1986) 68:281-284.	
	70	Sarkar, N.N. "Mifepristone: bioavailability, pharmacokinetics and use-effectiveness," <i>Eur. J. of Obstetrics & Gynecol and Reprod. Biol.</i> (2002), 101:113-120.	
	71	Schneider W. et al., "Effects of progesterone, promegestone and RU 486 on glucocorticoid receptor levels in primary cultures of mouse mammary epithelial cells," <i>J. Steroid. Biochem.</i> (1988), 29:599-604.	
	72	Schuitemaker, H. et al., "Biological phenotype of human immunodeficiency virus type 1 clones at different stages of infection: progression of disease is associated with a shift from monocytotropic to T-cell-tropic virus population," <i>J. Virol.</i> (1992) 66:1354-60.	
	73	Shibata, R. et al., "Mutational analysis of simian immunodeficiency virus from African green monkeys and human immunodeficiency virus type 2," <i>J. Med. Primatol.</i> (1990) 19:217-225.	

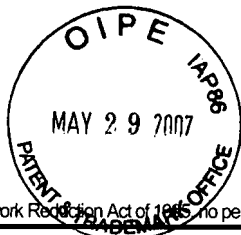
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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

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Sheet 6 of 6

Complete if Known

Application Number	10/561,603
Filing Date	March 29, 2007
First Named Inventor	Jong Joseph Kim
Art Unit	1615
Examiner Name	To Be Determined
Attorney Docket Number	VGX0001-100

NON PATENT LITERATURE DOCUMENTS

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	74	Shibata, R., et al., "Mutational analysis of the human immunodeficiency virus type 2 (HIV-2) genome in relation to HIV-1 and simian immunodeficiency virus SIV (AGM).," J. Virol. (1990)64:742-747.	
	75	Swahn, et al., "Plasma Levels of Antiprogestin RU 486 Following Oral Administration to Non-Pregnant and Early Pregnant Women," Contraception, vol. 34, no. 5 (Nov. 1986), pp. 469-481	
	76	Tsurufuji et al., "Blockade by antiglucoctocoids, actinomycin D and cycloheximide of anti-inflammatory action of dexamethasone against bradykinin," J. Pharmacol. Exp. Ther. (1980), 212: 225-231.	
	77	Valentin, A. et al., "In vitro maturation of mononuclear phagocytes and susceptibility to HIV-1 infection," J. Acquir. Immune Defic. Syndr (1991) 4:751-9.	
	78	Wagner B. L. et al., "The Novel Progesterone Receptor Antagonists RTI 3021-012 and RTI 3021-022 Exhibit Complex Glucocorticoid Receptor Antagonist Activities: Implications for the Development of Dissociated Antiprogestins," Endocrinology (1999), 140:14491458	
	79	Westervelt, P. et al., "Dual regulation of silent and productive infection in monocytes by distinct human immunodeficiency virus type 1 determinants," J. Virol. (1992) 66:3925-31.	
	80	Wong-Staal, F., et al., "Human immunodeficiency virus: the eighth gene," (1987) AIDS Res. Hum. Retroviruses 3:33-39	
	81	Yu, X.F., et al., "Open reading frame vpr of simian immunodeficiency virus encodes a virion-associated protein," J. Virol. (1990), 64:5688-5693.	
	82	Yuan, X., et al., "Human immunodeficiency virus vpr gene encodes a virion-associated protein," AIDS Res. Hum. Retroviruses (1990) 6:1265-1271.	
	83	Zack, J.A. et al., "HIV-1 production from infected peripheral blood T cells after HTLV-I induced mitogenic stimulation," (1988) Science .240:1026-9.	

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